

REMARKS

Claims 1-21 are pending and stand rejected. Claims 1, 9, and 17 are amended. Support for the amendments can be found, *inter alia*, in paragraphs [0034], [0040], and [0045] of the specification. No new matter is added herein.

Applicants have thoroughly reviewed the Office action, including the Examiner's remarks and the references cited therein. Applicants submit that the following remarks are fully responsive to the Office action, and that all pending claims are patentable over the cited references.

Rejection Under 35 U.S.C. § 103

The Examiner rejects claims 1-21 under 35 U.S.C. § 103 as obvious over U.S. Patent No. 4,938,220 to Mueller Jr. ("Mueller") in view of U.S. Patent No. 6,562,049 to Norlander et al. ("Norlander"). To establish a *prima facie* case of obviousness, the Examiner must demonstrate some suggestion or motivation to combine one or more references, with a reasonable expectation of success, to teach or suggest each and every claimed limitation. MPEP § 2142. Applicants contend that the Examiner has failed to meet this burden with respect to the rejected claims. In particular, no motivation exists to make the asserted combination, and the combination, even if proper, fails to teach or suggest the claimed invention.

I. No Motivation Exists to Make the Asserted Combination

Motivation to combine references may only be found in the teachings of the prior art, the nature of the problem to be solved, and the knowledge of persons of ordinary skill in the art. MPEP § 2143.01(I) (citing In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998)). Further, it is not sufficient that the asserted references *can* be combined; the prior art must also suggest the desirability of the combination. MPEP § 2143.01(III) (citing In re Mills, 916 F.2d 680 (Fed. Cir. 1990)). The burden of establishing that the combination is desirable rests squarely upon the Examiner. In re San Su Lee, 277 F.3d 1338 (Fed. Cir. 2002).

Mueller and Norlander are directed to divergent problems. Mueller mentions that continuous radiopaque bands interfere with catheter functions (for example, the venting of a balloon), and seeks to solve these problems through the use of a gapped radiopaque sleeve permitting unimpeded passage of a vent opening. Mueller, col. 1, lines 18-20 and col. 2, lines 60-63. Mueller does not teach or suggest that the catheter be splittable or include score lines. In fact, under many circumstances, it would be undesirable for the catheter to be splittable or scored, thus teaching away from both the asserted combination with Norlander and the claimed invention. Norlander, on the other hand, provides a longitudinally splittable introducer system for use along a complex, tortuous path. Norlander, col. 2, lines 8-15. In some embodiments, the Norlander introducer includes a radiopaque metal band, but does not teach or suggest the desirability of a radiopaque band with a score line enabling it to be splittable. *Id.*, col. 11, lines 1-2. Norlander also does not mention venting of balloons or vent openings that might suggest a splittable radiopaque marker.

Considering the disparate nature of the problems addressed by Mueller and Norlander, the fact that neither reference suggests the desirability of the other, much less the desirability of the present invention, and the fact that Mueller arguably teaches away from the claimed invention, Applicants contend that one of ordinary skill in the art simply would not be motivated to make the modifications suggested by the Examiner without the improper application of hindsight in light of the present invention. See In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000) ("Particular findings must be made as to the reason the skilled artisan, *with no knowledge of the claimed invention*, would have selected these components for combination in the manner claimed.") (emphasis added). Thus, Applicants respectfully submit that the Examiner has not carried the burden of establishing the desirability of the asserted combination, and therefore has not established that the rejected claims are *prima facie* obvious.

II. The Asserted Combination, Even if Proper, Would
Not Teach or Suggest the Claimed Invention

Applicants further submit that, even if one of ordinary skill in the art *did* combine the asserted references, the resultant combination would not teach or suggest the claimed invention.

A. Independent Claims 1 and 9 are Patentable
Over Mueller and Norlander

Claim 1 recites “at least one longitudinally extending marker score line running substantially along a length of said radiopaque marker, wherein said radiopaque marker *may be split into two or more pieces* along said at least one marker score line[.]” while claim 9 recites “at least one longitudinally extending marker notch running substantially along a length of said radiopaque marker, wherein said radiopaque marker *may be split into two or more pieces* along said at least one marker notch[.]” (Emphasis added.) That is, the claimed score line or notch acts as a stress concentrator to facilitate splitting the radiopaque marker into multiple pieces therealong. This is analogous to a perforated (“scored”) sheet of paper: the perforation permits one to easily split a single sheet of paper into multiple pieces.

Mueller, on the other hand, teaches a *unitary* semi-cylindrical radiopaque sleeve including an arcuate gap. Mueller, col. 1, lines 54-57. Mueller’s sleeve cannot be split into pieces along the gap; it will *always* be a single piece. Thus, Mueller does not teach or suggest that the “marker may be split into two or more pieces along said at least one marker score line” as recited in claim 1 or “along said at least one marker notch” as recited in claim 9.

The addition of Norlander does nothing to cure the shortcomings of Mueller. Though Norlander mentions a radiopaque metal band that may be included in the sheath (Norlander, col. 11, line 2), it does not disclose that the band is scored as recited in claim 1 or notched as recited in claim 9, much less that the band can be split into pieces. To the contrary, Norlander teaches scoring only the sheath. *Id.*, col. 6, lines 50-55.

Applicants respectfully submit that the asserted combination of references, even if proper, does not teach or suggest each and every element recited in either claim 1 or claim 9, and that those claims are therefore allowable. Claims 2-8 depend from claim 1, while claims 10-16 depend from claim 9. It is axiomatic that dependent claims are allowable over the same cited art as the allowable claims from which they depend. E.g. MPEP § 2143.03 (citing In re Fine, 837 F.2d 1071 (Fed. Cir. 1988)).

B. Dependent Claims 2, 5, 10, and 11 are Further Distinguishable Over the Asserted References

In addition, Applicants note that claim 2 recites "a *second* marker score line running substantially along said length of said radiopaque marker[.]" while claim 10 recites "a *second* marker notch running substantially along said length of said radiopaque marker[.]" (Emphasis added.) The asserted combination of references lacks these elements.

During a telephone conference on November 28, 2006, the Examiner indicated that she interpreted the terms "score line," "notch," and "gap" to encompass any absence of material. Thus, under the Examiner's view, Mueller's arcuate gap reads on a v-shaped notch in a piece of material by virtue of the removal of the material within the "V." Even assuming *arguendo* that the Examiner's interpretation is correct, Mueller teaches only a single, continuous absence of material, and thus only a single "notch" or "score line." Mueller cannot properly be read to disclose "a second" marker score line or notch, as there is no distinct second absence of material.

Further, Mueller teaches away from the inclusion of a second arcuate gap in the marker, insofar as a radiopaque sleeve with two arcuate gaps would be difficult to crimp about Mueller's inner tubular member. Furthermore, Mueller's second marker 26 is a "band of radiopaque material such as gold[.]" and does not include any absence of material. Mueller, col. 2, lines 31-39. Therefore, Mueller cannot be read to teach or suggest the claimed "second marker score line" or "second marker notch."

Nothing in Norlander cures these shortcomings. Thus, claims 2 and 10 are further distinguishable over the asserted combination of references. Claims 3-9 depend

from claim 2, while claims 11-16 depend from claim 10, and are allowable for at least the same reasons.

Applicants further point out that, even if one could properly regard the arcuate gap of Mueller as either a score line or a notch, the asserted combination of references would still fail to teach or suggest the invention of claim 5 and claim 11. Claim 5 recites that "said first sheath score line and said first marker score line are aligned; and said second sheath score line and said second marker score line are aligned[.]" while claim 11 recites that "said first sheath score line and said first marker notch are aligned; and said second sheath score line and said second marker notch are aligned."

Though the subject is not addressed in the Office action, Applicants submit that it is clear that neither Mueller nor Norlander teaches or suggests the recited relationship between the sheath score line and marker score line or marker notch, and thus the asserted combination necessarily fails to establish a *prima facie* case of obviousness as to claims 5 and 11. Claims 6-8 depend from claim 5, while claims 12-16 depend from claim 11, and are allowable for at least the same reasons.

C. Independent Claim 17 is Not Obvious
Over Mueller in View of Norlander

Claim 17 recites a "radiopaque marker defining a gap *substantially aligned with said sheath score line, wherein said first marker portion may be split apart from said radiopaque marker along said gap[.]*" (Emphasis added.) Applicants acknowledge that Mueller teaches a radiopaque marker defining a gap. As explained for claims 5 and 11, however, the asserted combination utterly fails to even suggest the claimed relationship between the gap of Mueller and the sheath score line of claim 17. Nor does Mueller teach that the "first marker portion may be split apart from said radiopaque marker along said gap;" as described at length above, Mueller's sleeve will *always* be a single, unitary piece incapable of division into smaller components.

Thus, the cited art fails to teach or suggest claim 17. Claims 18-21 depend from claim 17 and are allowable for at least the same reasons.

D. Dependent Claim 19 is Further Distinguishable
Over the Asserted Combination of References

Moreover, claim 19 recites “a second marker portion; and a second gap[.]” As discussed at length above, it is clear that Mueller teaches only a single marker portion (sleeve 11) and a single gap 12, and in fact teaches away from multiple marker portions and gaps. It is equally clear that Norlander does nothing to overcome this deficiency. Thus, claim 19 is further distinguished over the cited art. Claims 20 and 21, which depend from claim 19, are allowable for at least the same reasons.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-21 under 35 U.S.C. § 103.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance, and request that all rejections be withdrawn, that all pending claims be allowed, and that the application be passed to issue. If, for any reason, the Examiner finds the application to be in other than condition for allowance, the Examiner is invited to contact the undersigned in an effort to resolve any matter still outstanding before issuing another action.

Applicants have provided for a two (2) month extension of time concurrently herewith. If any further extension of time is deemed necessary for this submission to be considered timely, Applicants hereby petition therefor.

Authorization is hereby granted to charge any fees, including fees for any further extensions of time deemed necessary, to Deposit Account No. 50-1129 with reference to Attorney Docket No. 0B-044600US/82410-0054.

Respectfully submitted,

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Date: December 26, 2006

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